

Adverse Drug Reactions Recognising and Reporting

Adverse drug reactions (ADRs) are unwanted or harmful reactions to medicines that were taken under normal conditions of use.

These reactions are related to the medicines themselves rather than other factors.

Risk factors for ADRs

The following factors may increase the risk of experiencing an ADR:

- Age (children and older adults are more at risk due to differences in the renal, hepatic and cardiovascular systems)
- Polypharmacy
- Sex (some medicines are more likely to cause anaphylaxis in females)
- Smoking, which increases the risk of anaphylaxis
- Atopy, which is linked to latex allergy and anaphylaxis
- Exposure to latex.

(Patton & Borshoff 2018)

Adverse Drug Event or Adverse Drug Reaction?

An Adverse Drug Event (ADE)

is any harm from drug use (error, overdose, or reaction)

An Adverse Drug Reaction (ADR)

is a specific type of ADE - a noxious, unintended response directly caused by the drug itself at normal doses

Most Adverse Drug Reactions can be divided into TWO main categories:

Type A

ADRs are predictable, dose-dependent reactions related to the pharmacology of the particular medicine (e.g. constipation caused by medicine that prevents diarrhoea).

They are the most common type of ADR.

Type A reactions include:

- o Toxic effects
- o Side effects
- o Secondary effects

Type B

ADRs are hypersensitivity reactions (allergic reactions).

They are unpredictable and not dose-dependent.

Type B reactions accounts for 10-15% of ADRs.

***Anaphylaxis is a Type B Adverse Drug reaction.**

Reporting Adverse Drug Reactions

ADRs are encouraged to be reported to Therapeutic Goods Administration. This helps contribute to their safety monitoring. You should report:

- Any suspected ADRs caused by a new therapeutic good
- Any suspected medicine and/or vaccine interactions
- Any unexpected ADRs that do not appear in the medicine's CMI, Product Information or product labelling
- Any serious ADRs, including those suspected of causing:
 - o Death or Danger to life
 - o Hospitalisation (or prolonged hospitalisation)
 - o Absence from productive activity
 - o Increased investigational or treatment costs
 - o Birth defects.

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Most Important: Document the reaction in the resident's record!

Importance of Reporting

Ensuring the safe use of medicines is a crucial component of patient safety. Any known or new adverse drug reaction(s) should be documented, monitored and communicated appropriately to prevent re-exposure. The strengthened Aged Care Quality Standards (Outcome 5.3) requires aged care providers to establish processes for reporting adverse medicine and vaccine effects to the Therapeutic Goods Administration.



To report an adverse drug reaction (ADR) in Australia, use the Therapeutic Goods Administration (TGA) website, or call the **Adverse Event Medicine Line at 1300 633 424 (1300 MEDICINE)**

Information about common and significant ADRs for a specific medicine can be found in that medicine's consumer medicines information (CMI) leaflet. CMIs can be found on the Australian Register of Therapeutic Goods. (TGA 2020).